Attachment 4

K 013890

DEC 1 1 2001

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510(k) Summary

Surgical Dynamics Meniscal Staple

United States Surgical
150 Glover Avenue
Norwalk, CT 06856
USA

DEVICE DESCRIPTION

The currently marketed Surgical Dynamics Meniscal Staple is an absorbable implantable staple composed of a lactide/glycolide polymer. The staple consists of two rigid resorbable barbed legs connected by a length of resorbable, flexible braided filament. The staple is designed to facilitate meniscal repair in the vascular zone of the meniscus.

INDICATIONS FOR USE

The Surgical Dynamics Meniscal Staple is intended for the repair of vertical longitudinal full thickness tears (i.e., bucket-handle) in the red-red and red-white zones.

SUBSTANTIAL EQUIVALENCE*

The modified Surgical Dynamics Meniscal Staple was claimed to be substantially equivalent* to the currently marketed version of the device. Information pertaining to this device was provided in the submission.

*Any claim of substantial equivalence is made exclusively in regard to the U.S. Food, Drug and Cosmetic Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Ms. Jenny Schuck
Regulatory Affairs Senior Associate
United States Surgical
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K013890
Device Name: Surgical Dynamics Meniscal Staple
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 20, 2001
Received: November 23, 2001

Dear Ms. Schuck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

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Indications for Use Statement

510(k) Number K013890

Device Name

Surgical Dynamics Meniscal Staple

Indications For Use

The Surgical Dynamics Meniscal Staple is intended for the repair of vertical longitudinal full thickness tears (i.e., bucket-handle) in the red-red and red-white zones.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes OR Over-The-Counter Use: No
(Per 21 CFR 801.109)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013890